Expedited Procedure
Under 37 C.F.R. § 1.116

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Manne Satyanarayana Reddy et al. Examiner: Patricia L. Morris

Application No.: 10/716,200 Group: 1625

Filed: November 18, 2003

For: CRYSTALLINE ESOMEPRAZOLE COMPOUNDS
AND PROCESS FOR THE PREPARATION THEREOF

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE

Sir:

This Response is submitted in reply to the Office Action that was mailed on April 6, 2006 for the subject application. A response is due by July 6, 2006. Accordingly, this Response is being timely filed.

Claims 1, 3-9, 11-17 and 19-34 are pending in the above-identified patent application. Claims 19-32 have been withdrawn subject to a restriction requirement, and claims 1, 3-9, 11-17, and 33-34 have been rejected. Applicants are not amending, adding, or canceling any claims. Accordingly, claims 1, 3-9, 11-17, and 33-34 remain under examination.

In view of the following discussion, applicants respectfully request that the Examiner reconsider and withdraw the final rejections of the examined claims, made in the outstanding Office Action.

Restrictions.

The Examiner has acknowledged applicants' election of Group I, with traverse, in the reply filed July 19, 2005 on the grounds that there is no burden on the Examiner to search all the inventions. The Examiner states that the traversal on the grounds that there is no burden on the Examiner to search all the inventions is not persuasive. The Examiner has therefore made the restriction requirement FINAL.

Rejection of Claims 1, 3-9, 11-17, and 33-34 under 35 U.S.C. § 102(a) and/or (e) as being anticipated by *Cotton et al.*

The Examiner has finally rejected claims 1, 3-9, 11-17, and 33-34 under 35 U.S.C. § 102(a) and/or (e) as being anticipated by United States Patent No. 6,369,085 (*Cotton et al.*). The Examiner states that *Cotton et al.* discloses the instant compound at Example 1 and recites that magnesium S-omeprazole hydrates are highly crystalline, *Cotton et al.* at column 2, lines 47-50. The Examiner states that applicants' arguments are directed to a process for making the compound and not claiming the compound and processes for making the compound. The Examiner states that a novel chemical product is identified first by its "chemical nature", i.e., elemental and atom content and it is well known that many pharmaceutical solids exhibit polymorphism which is frequently defined as the ability of a substance to exist as two or more crystalline phases that have different arrangements and/or conformations of the molecules in the crystal lattice. The Examiner argues that polymorphs are different crystalline forms of the same pure substance in which the molecules have different arrangements and/or different conformations of the molecules. Applicants traverse the Examiner's rejection.

Applicants' claims 1, 6, and 33-34 recite "a crystalline form II of esomeprazole magnesium trihydrate, having substantially the same X-ray diffraction pattern as shown in Figure 1."

The *Cotton et al.* reference discloses a form of the (-)-enantiomer of 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)-methyl]sulfinyl]-1H-benzimidazole, a form of the magnesium salt of the S-enantiomer of omeprazole trihydrate. Example 1 of *Cotton et*

al. discloses a method for preparing S-omeprazole magnesium salt trihydrate, which method includes adding water to wet crystals of the magnesium salt of S-omeprazole, heating the mixture to 38°C. with stirring for 3 hours, filtering the crystals, and drying the crystals *in vacuo*.

As set out in applicants' specification, *Cotton et al.* "discloses esomeprazole magnesium trihydrate prepared from the corresponding potassium salt, precipitated with acetone, and treated with water. The crystalline form of the '085 patent will be designated herein as crystalline form I." *Applicants' specification at page 1, lines 25-28.* The Examiner does not deny that applicants' specification teaches any person skilled in the art how to make the crystalline form II of esomeprazole magnesium trihydrate, having substantially the same X-ray diffraction pattern as shown in Figure 1 recited in applicants' claims nor can the Examiner point to any passage in *Cotton et al.* disclosing applicants' method for making crystalline form II, or establishing a reasonable basis for concluding that the prior art compound disclosed by *Cotton et al.* meets all the limitations of the applicants' claims.

Applicants submit that *Cotton et al.* does not anticipate applicants' claims. *Cotton et al.* precipitates the magnesium salt of S-omeprazole from water. Applicants' process for preparing a trihydrate of esomeprazole magnesium in the form of a crystalline solid process comprises (a) providing esomeprazole magnesium as a solution in a ketone-containing solvent; (b) cooling said solution so that a solid mass separates; and (c) isolating the separated solid mass, which is the trihydrate of esomeprazole magnesium in the form of a crystalline solid. *Applicants' specification at pages 9-10, bridging paragraph.* Cotton et al. does not teach precipitation of esomeprazole magnesium from a ketone-containing solvent but rather teaches precipitation of the magnesium salt of S-omeprazole from water. *Cotton et al.* also does not disclose applicants' crystalline form II of esomeprazole magnesium trihydrate having substantially the same X-ray diffraction pattern as shown in Figure 1. In summary, *Cotton et al.* does not teach each and every element of applicants' crystalline form II of esomeprazole magnesium trihydrate. Accordingly, *Cotton et al.* does not anticipate applicants' claims under 35 U.S.C. § 102.

Polymorphs arise when molecules of a compound are ordered in the solid state in distinct ways. By varying the temperature of the solution and using different solvents,

different polymorphs can be formed. Although identical in chemical composition, polymorphs can have very different properties. Polymorphs are distinguishable by various analytical techniques, especially X-ray powder diffraction patterns.

Under 35 U.S.C. § 102, anticipation requires that each and every element of the claimed invention be disclosed in the prior art. *Akzo N.V. v. U.S. International Trade Commission*, 1 USPQ2d 1241, 1245 (Fed. Cir. 1986), cert. denied, 482 U.S. 909 (1987). Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration. *W.L. Gore & Associates v. Garlock, Inc.*, 220 USPQ 303, 313 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984). Anticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim. *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 221 USPQ 481, 485 (Fed. Cir. 1984) (emphasis added). We think the precise language of 35 U.S.C. §02 that "a person shall be entitled to a patent unless," concerning novelty and unobviousness, clearly places a burden of proof on the Patent Office which requires it to produce the factual basis for its rejection of an application under §102 and §103. *In re Warner*, 154 USPQ 173, 177 (C.C.P.A. 1967), cert. denied, 389 U.S. 1057 (1968).

Hence, the Examiner's rejection of claims 1, 3-9, 11-17, and 33-34 under 35 U.S.C. §102(a) and/or (e) as being anticipated by *Cotton et al.* should be withdrawn.

Rejection of Claims 1, 3-9, 11-17, and 33-34 under 35 U.S.C. §103(a) as being unpatentable over *Cotton et al.* in view of *Bohlin et al.*, *Lindberg et al.*, *Haleblian et al.*, *Muzaffar et al.*, *Chemical & Engineering News*, *US Pharmacopia*, and *Concise Encyclopedia Chemistry.*

The Examiner has finally rejected claims 1, 3-9, 11-17, and 33-34 under 35 U.S.C. § 103(a) as being unpatentable over *Cotton et al.* in view of United States Patent No. 6,162,816 (*Bohlin et al.*), United States Patent No. 6,875,872 (*Lindberg et al.)*, *J. of Pharm. Sciences*, (1969), 58, pp 911-929 (*Haleblian et al.*), *J. of Pharmacy* (Lahore) 1979, 1(1), 59-66 (*Muzaffar et al.*), *Chemical & Engineering News*, Feb. 2003 (*C&E News*), *US Pharmacopia*, 1995, pp. 1843-1844 (*USP*), and *Concise Encyclopedia*

Chemistry, pages 872-873 (1993) (*CEC*). The Examiner states that *Cotton et al.* discloses the instant compound at Example 1. The Examiner further states that *Bohlin et al.* and *Lindberg et al.* teach that s-omeprazole and its salts can exist in different crystalline states and that *Muzaffar et al.* and *Haleblian et al.* teach that compounds can exist in amorphous forms as well as in crystalline forms (*Bohlin et al.* at column 1, lines 58-63, *Muzaffar et al.* at page 60). The Examiner argues that *C&E News*, *USP*, and *CEC* teach that at any particular temperature and pressure, only one crystalline form is thermodynamically stable. The Examiner concludes that the claimed crystalline form as well as its relative selectivity of properties *vis-à-vis* the known compound are suggested by the references and it would be obvious in view of the references that the instant compound would exist in different crystalline forms.

The Examiner asserts that one having ordinary skill would find the claims obvious because the instant claims differ from the known product merely by forms and the physical properties innate to the forms and it is well recognized that many solids exhibit polymorphism, which is the innate nature of the particular drug. The Examiner also argues that it is well recognized that the different polymorphs will display different physical properties such as X-ray diffraction, melting point, etc. The Examiner concludes that a product, which is merely a different form of known, compounds, notwithstanding that some desirable results are obtained therefrom, are unpatentable. Applicants traverse the Examiner's rejection.

As set out above, claims 1, 6, and 33-34 recite a "crystalline form II of esomeprazole magnesium trihydrate, having substantially the same X-ray diffraction pattern as shown in Figure 1."

The *Bohlin et al.* reference discloses S-omeprazole in a neutral form, wherein the form is in a solid state, preferably in a partly crystalline or substantially crystalline state, such as form A or form B.

The *Lindberg et al.* reference discloses the magnesium salt of (-)-omeprazole in an optical purity of at least about 94% enantiomeric excess.

The *Haleblian et al.* reference states that polymorphism is the ability of any compound to crystallize as more than one distinct crystal species and different polymorphs of a given compound are, in general, as different in structure and properties

as the crystals of two different compounds. *Haleblian et al.* states that solubility, melting point, density, hardness, crystal shape, optical and electrical properties, vapor pressure, and the like, vary with the polymorphic form and it should be possible to obtain different crystal forms of a drug with different performance properties. (*Haleblian et al.* at p. 911, column 2, top paragraph).

The *Muzaffar et al.* reference states that about one in every three organic compounds exhibits polymorphic behavior. The differences are primarily in crystalline structure which give rise to different physical properties. The molecules of drugs exhibit different space-lattice arrangements in the crystal form from one polymorph to the other, and have different physical properties such as density, melting point, dissolution rate, solubility, hardness, crystal shape, crystal habit, friability, and optical properties. (*Muzaffar et al.* at p. 60, middle paragraph).

C&E News, *USP*, and *CEC* merely teach that at any particular temperature and pressure, only one crystalline form is thermodynamically stable.

Applicants submit that the present claims are not rendered obvious by *Cotton et al.* in view of *Bohlin et al.*, *Lindberg et al.*, *Haleblian et al.*, *Muzaffar et al.*, *C&E News*, *USP*, and *CEC*. *Cotton et al.* precipitates the magnesium salt of S-omeprazole from water. Applicants' process for preparing a trihydrate of esomeprazole magnesium in the form of a crystalline solid process comprises (a) providing esomeprazole magnesium as a solution in a ketone-containing solvent; (b) cooling said solution so that a solid mass separates; and (c) isolating the separated solid mass, which is the trihydrate of esomeprazole magnesium in the form of a crystalline solid. *Applicants' specification at pages 9-10, bridging paragraph.* Cotton et al. does not teach to precipitate esomeprazole magnesium from a ketone-containing solvent but rather teaches to precipitate the magnesium salt of S-omeprazole from water. Neither *Cotton et al.*, nor the secondary references of *Bohlin et al.*, *Lindberg et al.*, *Haleblian et al.*, *Muzaffar et al.*, *C&E News*, *USP*, and *CEC*, disclose applicants' crystalline form II of esomeprazole magnesium trihydrate, having substantially the same X-ray diffraction pattern as shown in Figure 1.

The Examiner apparently would invoke a *per se* rule of obviousness, e.g., that merely changing the form, purity, or another characteristic of an old product, the utility

remaining the same as that for the old product, does not render the claimed product patentable. The Examiner argues that the crystalline form II of esomeprazole magnesium trihydrate recited in claim 1 is merely a different polymorphic form of the compound disclosed by *Cotton et al* and accordingly, the subject matter sought to be patented in applicants' claims 1, 3-9, 11-17, and 33-34 under 35 would have been *prima facie* obvious in view of *Cotton et al.* and the secondary references. As stated in *In re Ochiai*, 71 F.3d 1565, 1572, 37 USPQ2d 1127, 1133 (Fed. Cir. 1995):

> The use of *per se* rules, while undoubtedly less laborious than a searching comparison of the claimed invention including all its limitations with the teachings of the prior art, flouts section 103 and the fundamental case law applying it. *Per se* rules that eliminate the need for fact-specific analysis of claims and prior art may be administratively convenient for PTO examiners and the Board. Indeed, they have been sanctioned by the Board as well. But reliance on *per se* rules of obviousness is legally incorrect and must cease.

Moreover, the Examiner has not adequately explained how a person having ordinary skill would have been lead from "here to there," that is from the *Cotton et al.* compound to the crystalline form II of esomeprazole magnesium trihydrate recited in applicants' claims. These principles were discussed by the Board of Patent Appeals and Interferences in the unpublished decision of *Ex parte Andrews*, Appeal No. 2002-0941 (Application No. 09/166,445, now U.S. Patent 6,713,481), dealing with a similar rejection, and *Andrews* held that the controlling law can be found in *In re Cofer*, 354 F.2d 664, 148 USPQ 268 (CCPA 1966). The rejection must be based on scientific facts.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in

the prior art and not based on applicant's disclosure. *In re Vaeck,* 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). MPEP 706.02(j)

The initial burden is on the examiner to provide some suggestion of the desirability of doing what the inventor has done. "To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." *Ex parte Clapp,* 227 USPQ 972. 973 (Bd. Pat. App. & Inter. 1985). MPEP 706.02(j)

Obviousness of a composition or process must be predicated on something more than it would be obvious "to try" the particular component recited in the claims or the possibility it will be considered in the future, having been neglected in the past. *Ex parte Argabright et al.* (POBA 1967) 161 USPQ 703. There is usually an element of "obvious to try" in any research endeavor, since such research is not undertaken with complete blindness but with some semblance of a chance of success. "Obvious to try" is not a valid test of patentability. *In re Mercier* (CCPA 1975) 515 F2d 1161, 185 USPQ 774; *Hybritech Inc. v. Monoclonal Antibodies. Inc.* (CAFC 1986) 802 F2d 1367, 231 USPQ 81; *Ex parte Old* (BPAI 1985) 229 USPQ 196; *In re Geiger* (CAFC 1987) 815 F2d 686, 2 USPQ2d 1276. *In re Dow Chemical Co.* (CAFC 1988) F2d, 5 USPQ2d 1529. Patentability determinations based on that as a test are contrary to statute. *In re Antonie* (CCPA 1977) 559 F2d 618, 195 USPQ 6; *In re Goodwin et al.* (CCPA 1978) 576 F2d 375, 198 USPQ 1; *In re Tomlinson et al.* (CCPA 1966) 363 F2d 928, 150 USPQ 623. A rejection based on the opinion of the Examiner that it would be "obvious to try the chemical used in the claimed process which imparted novelty to the process does not meet the requirement of the statute (35 U.S.C. § 103) that the issue of obviousness be based on the subject matter as a whole. *In re Dien* (CCPA 1967) 371 F2d 886, 152 USPQ 550; *In re Wiaains* (CCPA 1968) 397 F2d 356, 158 USPQ 199; *In re Yates* (CCPA 1981) 663 F2d 1054, 211 USPQ 1149. Arguing that mere routine experimentation was involved overlooks the second sentence of 35 USC § 103. *In re Saether* (CCPA 1974) 492 F2d 849,181 USPQ. 36. The issue is whether the experimentation is within the teachings of the prior art. *In re Waymouth et al.* (CCPA

1974) 499 F2d 1273, 182 USPQ 290. The fact that the prior art does not lead one skilled in the art to expect the process used to produce the claimed product would fail does not establish obviousness. *In re Dow Chem. Co.* (CAFC 1988) 5 USPQ2d 1529.

The provisions of Section 103 must be followed realistically to develop the factual background against which the Section 103 determination must be made. It is not proper within the framework of Section 103 to pick and choose from any one reference only so much of it as will support a given position to the exclusion of other parts necessary for the full appreciation of what such reference fairly suggest to one of ordinary skill in the art. The references of record fail to teach or suggest applicant's invention as a whole.

Hence, the Examiner's rejection of claims 1, 3-9, 11-17, and 33-34 under 35 U.S.C. §103(a) as being unpatentable over *Cotton et al.* in view of *Bohlin et al.*, *Lindberg et al.*, *Haleblian et al.*, *Muzaffar et al.*, *C&E News*, *USP*, and *CEC* should be withdrawn.

Rejection of Claims 1, 3-9, 11-17, and 33-34 under 35 U.S.C. § 112, first paragraph.

The Examiner has finally rejected Claims 1, 3-9, 11-17, and 33-34 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner states that there is a lack of description as to whether the compositions are able to maintain the compound in the crystalline form claimed. The Examiner asserts that processing a compound into a pharmaceutical composition could create a different form than the crystalline form being claimed or even back to the compound itself. The Examiner states that disclosure of X-ray diffraction patterns for pharmaceutical compositions comprising the crystalline forms are lacking in the specification and the X-ray diffraction patterns in Figure 1 and infrared spectra only supports the crystalline form of magnesium esomperazole trihydrate.

The Examiner states that there are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5)

the level of predictability in the art, 6) the amount of direction provided by the inventor, 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. *In re Wands*. 858 F.2d 731, 737,8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Applicants traverse the Examiner's rejection.

The Examiner states that polymorphs may undergo transformation when being formulated into pharmaceutical compositions but polymorphism and crystallization may be mastered from start to finish. The Examiner's position that applicants' polymorphs may undergo transformation when being formulated into compositions is only speculation.

Applicants' specification need describe the invention only in such detail as to enable a person skilled in the most relevant art to make and use it. When an invention involves distinct arts, that specification is adequate which enables the adepts of each art, those who have the best chance of being enabled, to carry out the aspect proper to their specialty.

> The question is whether the disclosure is sufficient to enable those skilled in the art to practice the claimed invention, hence the specification need not disclose what is well known in the art. *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.,* 221 USPQ 481, 489 (Fed. Cir. 1984)

> It has been consistently held that the first paragraph of 35 U.S.C. § 112 required nothing more than objective enablement... In satisfying the enablement requirement, as application need not teach, and preferably omits that which is well-known in the art.....How such a teaching is set forth, whether by the use of illustrative examples or by broad descriptive terminology, is of no importance since a specification which teaches how to make and use the invention in terms which correspond in scope to the claims must be taken as complying with the first paragraph of 35 U.S.C. §112 unless there is reason to doubt the objective truth of the statements relied upon therein for enabling support. .
>
> The error we see in *Staehelin's* approach to the question before us is that *Staehelin* would require a patent specification to be a blueprint, which, if followed, would unfailingly reproduce exactly an applicant's claimed invention. However, the law does not require a specification to be a blueprint in order to satisfy the requirement for enablement under 35 U.S.C. §112, first paragraph. *Staehelin v. Secher,* 24 USPQ 2d 1513, 1516 (B.P.A.I. 1992)

Hence, the Examiner's rejection of claims 1, 3-9, 11-17, and 33-34 under 35 U.S.C. § 112, first paragraph, should be withdrawn.

Rejection of Claims 1, 6-9, 13-17, and 33-34 under 35 U.S.C. § 112, second paragraph.

The Examiner has finally rejected claims 1, 6-9, 13-17, and 33-34 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

The Examiner states that claims 1 and 33 (now amended to be claim 18) are drawn to the same scope. The Examiner states that claim 1 demonstrates that applicants are able to describe the instant hydrates without resorting to the process and so claim 33 (18) is improper. The Examiner argues that product-by-process claims are not proper in the same application where it has been demonstrated that the compound in question may be described by means of a chemical structure. Applicants traverse the Examiner's rejection.

M.P.E.P. 706.03(k) (Duplicate Claims) provides as follows:

> Inasmuch as a patent is supposed to be limited to only one invention or, at most, several closely related indivisible inventions, limiting an application to a single claim, or a single claim to each of the related inventions might appear to be logical as well as convenient. However, court decisions have confirmed applicant's right to restate (i.e., by plural claiming) the invention in a reasonable number of ways. Indeed, mere difference in scope between claims has been held to be enough.
>
> Nevertheless, when two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other claim under 37 C.F.R. § 1.75 as being a substantial duplicate of the allowed claim.

First, applicants submit that claims 1 and 33 (now amended claim 18) are different in scope since claim 1, as amended, recites "having substantially the same X-ray diffraction pattern as shown in Figure 1," which limitation is not recited in claim 33 (now amended claim 18). Second, the Examiner has not yet allowed either of these claims so it is not proper to require applicant to cancel one of these claims.

Hence, the Examiner's rejection of claims 1 and 33 (now 18) should be withdrawn.

Rejection to Claims 1, 6-9, 13-17, and 33-34 containing the trademark/trade name "Esomeprazole."

The Examiner has objected to claims 1, 6-9, 13-17, and 33-34 on the basis that the claims contain the trademark/trade name "esomeprazole." The Examiner states that where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. §112, second paragraph. Applicants traverse the Examiner's objections.

Applicants have described the structure of esomeprazole in applicants' specification as follows:

> Esomeprazole is the (S)(-)enantiomer of omeprazole, a sulfoxide which has an asymmetric center at the sulfur atom and exists as optical isomers (enantiomers). Esomeprazole ((S)(-)5-methoxy-2-[[(4-methoxy-3, 5-dimethyl-2-pyridinyl)-methyl] sulphinyl]-1H-benzimidazole) is the S(-)enantiomer of the drug omeprazole. Known forms of esomeprazole, and its salts, hydrates, and polymorphs, are gastric acid secretion inhibitors. *Applicants' specification at page 1, lines 13-18.*

Moreover, *Lindberg et al.*, which the Examiner has cited against applicants, recites as follows:

> The compound 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole, having the generic name omeprazole, and therapeutically acceptable alkaline salts thereof are described in U.S. Pat. No. 4,255,431 to Junggren et al., EP 5129 and EP 124 495, respectively. *Lindberg et al. at col. 1, lines 21-27.*

"Esomeprazole" is not a trademark or trade name, but is the name assigned to the compound by the U.S. Adopted Names ("USAN") Council, a cooperative effort of the American Medical Association, the U. S. Pharmacopeial Convention, Inc., and the American Pharmaceutical Association. Names selected by the USAN Council are normally used by the U.S. Food and Drug Administration as an official identifier for the

compound. Any pharmaceutical product sold in the United States and containing esomeprazole must be marked to show this name of the active ingredient.

The U.S. Food and Drug Administration has established criteria for an official drug name in 21 C.F.R. § 299.4, and this section states a preference for USAN adopted names.

Accordingly, the generic term "esomeprazole" does comply with the requirements of 35 U.S.C. §112, second paragraph, and the Examiner's objection to claims 1, 6-9, 13-17, and 33-34 should be withdrawn.

SUMMARY

In view of the foregoing Response, applicants request reconsideration pursuant to 37 C.F.R. § 112 and allowance of the claims examined in this application. Applicants request the Examiner to telephone the undersigned attorney should the Examiner have any questions or comments, which might be most expeditiously handled by a telephone conference. No fee is deemed necessary in connection with the filing of this Response. If any fee is required, however, authorization is hereby given to charge the amount of such fee to Deposit Account No. 50-3221.

Respectfully submitted,

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